# PSJ9 Exh 10

## STANDARD OPERATING PROCEDURE

| <b>SOP Number:</b> OPS-040-00                 | <b>Department: DISTRIBUTION OPERATIONS</b>           |  |
|---|--|--|
| Supersedes: NEW                               | Title: Suspicious Order Monitoring/ Order Monitoring |  |
|   | System   |  |
| ORIGINATOR                                    | Executive Management                                 |  |
| Signed By: Patrick Cochrane                   | Signed By: Patrick Cochrane                          |  |
| Title: Vice President, Logistics & Operations | Title: Vice President, Logistics & Operations        |  |
| Date:   | Date:  |  |
| Role: Preparer/Originator                     | Role: Reviewer                                       |  |
| Signature Meaning: Approval                   | Signature Meaning: Approval                          |  |
| DC Management                                 | Executive Management                                 |  |
| Signed By: Jay Spellman                       | Signed By: Al Paonnessa III                          |  |
| Title: FL Director, Logistics                 | Title: Executive Vice President & COO                |  |
| Date:   | Date:  |  |
| Role: Reviewer                                | Role: Reviewer                                       |  |
| Signature Meaning: Approval                   | Signature Meaning: Approval                          |  |
| DC Management                                 | Compliance Management                                |  |
| Signed By: Alberto Esteves                    | Signed By: Michael Cochrane                          |  |
| Title: OH Director, Logistics                 | Title: Director, Logistics Compliance                |  |
| Date:   | Date:  |  |
| Role: Reviewer                                | Role: Reviewer                                       |  |
| Signature Meaning: Approval                   | Signature Meaning: Approval                          |  |

### **REVISION HISTORY**

| Effective Date | Document<br>Number | Author           | Change Description |
|----------------|--------------------|------------------|--------------------|
|                | OPS-040-00         | Michael Cochrane |                    |
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#### STANDARD OPERATING PROCEDURE

#### 1.0 Scope

This directives contained in this SOP apply to all Anda and Anda Pharmaceutical employees that have or may have contact or involvement in the activities associated with Compliance and Distribution. This is to include, but not be limited to:

- \* Distribution Operations
- \* Compliance

#### 2.0 Purpose

To document the procedures involved in reviewing Held and/or Suspicious Orders.

#### 3.0 Procedure

3.1 System Formula:

- 1.
  2.
  3.
  4.
  5.
- 3.2 Review all held orders and determine the reason for additional product ordered. The following are release reasons for held orders
  - 1. 2. 3. 4. 5. 6. 7. 8.
- 3.4 Orders that exceed the above criteria and cannot be released with an appropriate reason listed above will be reported to the local DEA office for the applicable distribution center.
  - 1. A phone call to report the order to the local DEA office
  - 2. Follow up reports should be sent via FedEx

addlible dlykins